



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Service
Prior Authorization Criteria

HUMIRA® (adalimumab) and ENBREL® (etanercept)

Effective 03/05/2018

Prior Authorization Request Form

Prior authorization requests for Humira and Enbrel may be approved for their **FDA approved indications** provided the following criteria are met. Diagnoses must accompany all requests.

- Patient must meet minimum age per FDA indication and manufacturer recommendations (request will be denied if a diagnosis has not been provided);
- Initial treatment plan is done in consultation with an appropriate specialist (such as a dermatologist, gastroenterologist or rheumatologist); **AND**
- Negative tuberculin skin test before initiation of therapy; **AND**

THE FOLLOWING INDICATION-SPECIFIC CRITERIA MUST ALSO BE SATISFIED:

- **Ankylosing spondylitis:** must include documentation indicating ninety (90) day treatment history with NSAIDs (unless contraindicated).
- **Psoriasis** must have:
 1. Diagnosis of moderate to severe psoriasis; **AND**
 2. Prior treatment with a potent topical corticosteroid*; **AND**
 3. Prior treatment with a vitamin D analog (such as calcipotriene) *;
 4. Prior ninety (90) day treatment history with a disease-modifying agent (DMARD) such as methotrexate, cyclosporine, acitretin, etc.

*Please note: clinical studies have indicated that using a topical corticosteroid in combination with a vitamin D analog is more effective than using either agent separately.

- **Psoriatic arthritis:** must have a documented ninety (90) day history of NSAID therapy as well as ninety (90) day trials of at least two DMARDs.
- **Rheumatoid arthritis:** must have documented ninety (90) day trials of at least two DMARDs.
- **Juvenile idiopathic arthritis:** Prior authorization for Humira and Enbrel may be granted if the patient is two (2) years of age or older and has failed a ninety (90) day course of therapy with methotrexate.
- **Crohn's Disease:** Humira is approvable for moderate to severe Crohn's disease. *Enbrel is not indicated for treatment of Crohn's disease and will not be approved.*



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- **Pediatric Crohn's disease (moderate to severe):** For patients 6 years of age and older, prior authorization requests for Humira are approvable with documentation of an inadequate response to a 14-day trial of corticosteroids or an immunomodulator such as azathioprine, 6-mercaptopurine, or methotrexate.
- **Ulcerative Colitis:** Humira is approvable following failure or clinically significant adverse effects to a thirty (30) day course of aminosalicylates (e.g. sulfasalazine, mesalamine) requiring treatment for two (2) or more exacerbations using corticosteroids, such as prednisone. *Enbrel is not indicated for treatment of UC and will not be approved.*
- **Hidradenitis suppurativa:** Humira may be approved in patients 18 years of age or older who satisfy the following additional criteria:
 1. Has severe disease (Hurley stage III); **OR**
 2. Has moderate disease (Hurley stage II) despite treatment with an oral formulary tetracycline (i.e., doxycycline) OR topical clindamycin.
- **Uveitis:** Humira may be approved in patients diagnosed with non-infectious uveitis who are at least 18 years of age and who have failed to respond adequately to corticosteroid therapy, or in whom corticosteroid therapy is inappropriate.

References

- 1) Lexi-Comp drug monographs for Humira and Enbrel (7/11/2016)
- 2) Humira Package Insert (7/2016)
- 3) Enbrel Package Insert
- 4) 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
- 5) The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics
- 6) American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis
- 7) Crofford *Arthritis Research & Therapy* 2013, 15(Suppl 3):S2
- 8) J Braun *et al.* 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. *Ann Rheum Dis* 2011; 70:896-904
- 9) Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of psoriasis and psoriatic arthritis in adults. A national clinical guideline. Edinburgh (Scotland); Scottish Intercollegiate (SIGN), 2010 Oct (SIGN publication, no. 121 (217 references))
- 10) G Lichtenstein, S Hanauer *et al.* Management of Crohn's Disease in Adults. *Am J Gastroenterol* advance online publication, 6 January 2009
- 11) EDF Guideline for Hidradenitis Suppurativa / Acne Inversa (HS) - S1 Guideline – 2016-2017 (<file:///C:/Users/E033601/Downloads/Guideline-on-Hidradenitis-suppurativa-S1.pdf>)